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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,723	03/24/2006	Richard George Leonard Morgan	HO-P03185US0	6853

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EXAMINER	
LUKTON, DAVID	
ART UNIT	**PAPER NUMBER**
1654	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/538,723	MORGAN ET AL.	
	Examiner	Art Unit	
	David Lukton	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19,23,24,26,27,34 and 35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-19,23,24,26,27,34 and 35* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Pursuant to preliminary amendment, several claims have been amended, and claims 20-22, 25, 28-33 cancelled. Claims 1-19, 23, 24, 26, 27, 34, 35 are now pending.

. . . .

Restriction to one of the following inventions is required under 35 U.S.C. §121:

I. Claims 1-9, 16, 18, 19, drawn to a method of treating a disorder by administering a peptide, wherein there is no requirement or suggestion that a "cell penetration moiety" be present in the peptide, and further wherein there is no requirement or suggestion that a cytotoxic or chemotherapeutic agent be administered.

II. Claims 10-15, drawn to a method of treating a disorder by administering a peptide, wherein the peptide must comprise a "cell penetration moiety", but wherein there is no requirement or suggestion that a cytotoxic or chemotherapeutic agent be administered.

III. Claim 23, drawn to a method of reducing adverse effects of an agent by administering a peptide, wherein there is no requirement or suggestion that a "cell penetration moiety" be present in the peptide.

IV. Claims 24 and 27, drawn to a method of maintaining or expanding a stem cell population.

V. Claim 26, drawn to a method of treating a disorder by administering both of the following: (a) a cytotoxic or chemotherapeutic agent, and (b) a peptide, wherein there is no requirement or suggestion that a "cell penetration moiety" be present in the peptide.

VI. Claims 34-35, drawn to a composition which contains a peptide of the following formula: X_1-X_2-X_3-W-M-X_4-X_5-X_6-X_7

Claim 17 is not grouped. No claim dependence is recited, and so it cannot be determined which invention this claim is subgeneric to. In the event that claim 17 is amended to recite dependence on a specific claim, claim 17 will then be grouped appropriately.

The claimed inventions are distinct.

Inventions VI and I - V are actually not related as process of making and product made. The reason is that the Group VI claims require the presence of a pharmaceutical composition or carrier, whereas the claims of Groups I-V are drawn to a method of using a peptide *per se*.

If it had been the case that the claims of Groups I-V required the use of a pharmaceutical composition, then the standard form paragraph would apply, which is the following:

> The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP 806.05(f)).

Notwithstanding the foregoing, in the that Group VI is elected, and claims found allowable, claims that are drawn to a method of using the allowable compositions will be rejoined for further examination.

Inventions II and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations. (M.P.E.P. § 806.05(c)). In the

instant case, the combination as claimed does not require the particulars of the subcombination as claimed. The peptides of claim 1 can be used without the penetration enhancer. However, in the event that Group I is elected, and claims therein found allowable with the "comprising" language present (in reference to the peptide), it is likely that novelty would accrue to Group II. Similarly, Groups V and I are related as combination and subcombination. In the event that Group I is elected, and claims therein found allowable, it is likely that novelty would accrue to Group V, and it is also likely under that scenario that Group V claims would be rejoined with Group I.

Applicant is advised that for the response to this requirement to be complete, an election of the invention to be examined must be indicated, even if the requirement is traversed (37 C.F.R. 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

. . . .

In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect disclosed species (as follows) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

In the event that Group I is chosen for initial examination, election of each of the following is required:

a) a specific disorder that is to be treated in the elected method;

b) a specific cell type which is displaying aberrant division;

c) a specific peptide that falls within the scope of claim 1;

d) the route of administration in the elected method.

. . . .

In the event that Group II is chosen for initial examination, election of each of the following is required:

a) a specific disorder that is to be treated in the elected method;

b) a specific cell type which is displaying aberrant division;

c) a specific peptide that falls within the scope of claim 10;

d) the route of administration in the elected method.

. . . .

In the event that Group III is chosen for initial examination, election of each of the following is required:

a) a specific disorder that is to be treated in the elected method;

b) a specific cell type which is displaying aberrant division;

c) a specific peptide that falls within the scope of claim 1;

d) the route of administration in the elected method;

e) a specific cytotoxic or chemotherapeutic agent, the side effects of which applicants are endeavoring to mitigate;

f) a specific "side effect" which applicants are endeavoring to mitigate.

. . . .

In the event that Group IV is chosen for initial examination, election of each of the following is required:

a) a specific peptide that falls within the scope of claim 1;

b) a specific type of stem cells (e.g., haematopoietic stem cells, neural stem cells, hepatic stem cells, or embryonic stem cells);

c) one of the following: (i) a method of maintaining or expanding a stem cell population *ex vivo*, or (ii) a method of maintaining or expanding a stem cell population *in vivo*.

. . . .

In the event that Group V is chosen for initial examination, election of each of the following is required:

a) a specific disorder that is to be treated in the elected method;

b) a specific cell type which is displaying aberrant division;

c) a specific peptide that falls within the scope of claim 1;

d) the route of administration in the elected method.

e) a specific cytotoxic or chemotherapeutic agent that is administered;

f) one of the following: (i) the peptide of claim 1 and the cytotoxic / chemotherapeutic agent are administered concomitantly, or (ii) the peptide of claim 1 and the cytotoxic / chemotherapeutic agent are administered sequentially.

. . . .

In the event that Group VI is chosen for initial examination, election of each of the following is required:

a) a specific peptide that falls within the scope of claim 1;

b) a specific carrier;

c) one of the following: (i) the elected composition contains a cytotoxic or chemotherapeutic agent or (ii) the elected composition does not contain a cytotoxic or chemotherapeutic agent

d) in the event that the elected composition contains a cytotoxic or chemotherapeutic agent, election is required of a specific cytotoxic or chemotherapeutic agent that is present.

. . . .

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are witten in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. . 103 of the other invention.

. . . .

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

DAVID LUKTON, PH.D.
PRIMARY EXAMINER